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United States Senate

COMMITTEE ON SMALL BUSINESS & ENTREPRENEURSHIP

WASHINGTON, DC 20510-6350

July 11, 2002

Dr. Lester Crawford, D.V.M, Ph.D.
Deputy Commissioner
United States Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-0001

Dear Mr. Commissioner:

Industry representatives have informed me of the current efforts to harmonize U.S. standards for indoor tanning with international standards, in particular those of the International Electrotechnical Commission (IEC) being undertaken by FDA's Office of Science and Technology in the Center for Devices and Radiological Health. They have also informed me that this process threatens to cause significant economic harm to many of their members.

While the mandate for this harmonization may derive from the Food and Drug Administration Modernization Act of 1997, (See P.L. 105-115, Sec. 204 (a)), the small business implications of this process must not be forsaken. The Small Business Regulatory Enforcement Fairness Act (SBREFA) requires that when agencies are required to issue regulations in accordance with the Administrative Procedure Act, they must determine whether a regulation will have a "significant economic impact on a substantial number of small entities." (See 5 U.S.C. § 605(b).) If the regulation will have such an impact, the agency must conduct an Initial Regulatory Flexibility Analysis as specified in 5 U.S.C. § 603.

The tanning industry is comprised of many small businesses who are likely to be impacted by FDA's harmonization process. I expect FDA to consider fully these impacts, consistent with its obligations under SBREFA and the Regulatory Flexibility Act.

If you have any questions, please feel free to contact Emilia DiSanto of my staff at (202) 224-

Sincerely,



Christopher S. Bond
Ranking Member